Bayer

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June 14, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1060
Rockville, MD 20852

Re: Docket No. 00D-1542, Draft Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures, Time Stamps

Bayer Corporation appreciates the opportunity to provide comments on the Draft Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures, Time Stamps. As a manufacturer of pharmaceuticals, biologicals, medical devices, animal health products, and consumer care products, 21 CFR Part 11 Electronic Records and Electronic Signatures has a significant impact on the Bayer Corporation organization. The comments included as an attachment to this letter represent the current thinking of subject matter experts within Bayer Corporation.

In general, we felt that the guidance document prescribes a level of technical requirements that are currently not practical based on a cost of implementation versus benefits. The requirements in the guidance document should be less strongly worded to better reflect the purpose of a guidance document. We recommend that compliance with the intention of Part 11 regarding time stamps be achieved through procedures and employee training. In addition, the document does not provide guidance on error tolerance for time stamps. Time variation can be a problem when validating and maintaining a system, especially if the system interfaces with other systems. A job queue, heavy network traffic, or basic system differences may become an issue when verifying signature and audit trail time stamps. A margin of error should be allowed on networked and stand-alone systems as long as the sequence of events is correct and accurately captured.

If you have any questions regarding our comments, please contact me.

Sincerely,

00D-1542 C5

Elizabeth Gaipa

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Attachment: Bayer Corporation Comments Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures, Time Stamps